Electronically Filed November 7, 2008

APPELLANTS' BRIEF Address to: Mail Stop Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application Number	10/674,695
	Confirmation Number	5085
	Attorney Docket No.	ADCI-073
	Filing Date	September 30, 2003
	First Named Inventor	Pierce, Robin D.
	Examiner	Olsen, Kaj K.
	Art Unit	1795
	Title: *Low Volume Electrochemical Biosensor*	

Sir:

This Brief is filed in support of Appellants' appeal from the Examiner's Rejection dated July 2, 2008. No claims have been allowed, and Claims 1, 3, 6-16, 18, and 21-34 are pending. Claims 1, 3, 6-16, 18, and 21-34 are appealed. A Notice of Appeal was filed on September 23, 2008. As such, this Appeal Brief is timely filed.

The Board of Appeals and Interferences has jurisdiction over this appeal pursuant to 35 U.S.C. § 134.

Provided herewith is an authorization to charge the amount of $540.00 to cover the fee required under 37 C.F.R. § 41.20(b)(2) for filing Appellants' Brief. In the unlikely event that the fee transmittal or other papers are separated from this document and/or other fees or relief are required, Appellants petition for such relief, including extensions of time, and authorize the Commissioner to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to deposit account number 50-8015, reference no. ADCI-073.

TABLE OF CONTENTS

REAL PARTY IN INTEREST

The inventors named on this patent application have assigned their entire rights to the invention to Abbot Laboratories.

RELATED APPEALS AND INTERFERENCES

There are currently no other appeals or interferences known to Appellants, the undersigned Appellants' representative, or the assignee to whom the inventors assigned their rights in the instant case, which would directly affect or be directly affected by, or have a bearing on the Board's decision in the instant appeal.

STATUS OF CLAIMS

The present application was filed on September 30, 2003 with Claims 1-28. During the course of prosecution, Claims 29-34 were added, Claims 2, 4, 5, 17, 19, and 20 were canceled, and no Claims were withdrawn. Accordingly, Claims 1, 3, 6-16, 18, and 21-34 are pending and under examination in the present application, all of which are appealed herein.

STATUS OF AMENDMENTS

No amendments to the Claims were filed subsequent to issuance of the Final Rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

Below is a description of each independent appealed claim and where support for each can be found in the specification.

Independent Claim 1 claims a biosensor for determining the concentration of an analyte in a liquid sample (see specification at page 1, lines 6-9). The biosensor comprises (a) an electrode support (see specification at page 9, lines 2-4), (b) an arrangement of electrodes disposed on the electrode support (see specification at page 7, lines 12-20), the arrangement of electrodes comprising at least a working electrode comprising conductive ink (see specification at page 9, lines 5-6), wherein the conductive ink comprises at least one enzyme, at least one mediator, and a polymer that provides hydrophilic domains in the conductive ink (see specification at page 22,

lines 13-16, and at page 23, lines 1-2), (c) a first conductive track leading from the working electrode to an electrical contact associated with the working electrode, and (d) a second conductive track leading from a second electrode to an electrical contact associated with the second electrode (see specification at page 9, lines 2-8).

Claim 3 depends from Claim 1 and claims the biosensor of Claim 1, wherein the at least one mediator is selected from the group consisting of organometallic compounds, organic compounds, and coordination compounds with inorganic or organic ligands (see specification at page 17, lines 14-17).

Claim 6 depends from Claim 1 and claims the biosensor of Claim 1, wherein the biosensor requires a low volume of sample to trigger an electrochemical reaction (see specification at page 16, lines 1-3, and at page 22, lines 10-12).

Claim 7 depends from Claim 1 and claims the biosensor of Claim 1, wherein spacing between the working electrode and the second electrode does not exceed about 200 micrometers (see specification at page 16, lines 7-11).

Claim 8 depends from Claim 1 and claims the biosensor of Claim 1, wherein the working electrode has an area of from about 0.5mm^2 to about 5 mm^2 (see specification at page 14, lines 17-20, and at page 15, lines 26-31).

Claim 9 depends from Claim 1 and claims the biosensor of Claim 1, wherein the electrode arrangement further comprises a trigger electrode (see specification at page 10, lines 18-25).

Claim 10 depends from Claim 1 and claims the biosensor of Claim 1, wherein the electrode arrangement further comprises a third electrode (see specification at page 10, lines 26-31).

Claim 11 depends from Claim 10 and claims the biosensor of Claim 10, wherein the electrode arrangement further comprises a fourth electrode, the fourth electrode having the function of a trigger electrode (see specification at page 10, lines 32-34, and at page 11, lines 1-2).

Claim 12 depends from Claim 1 and claims the biosensor of Claim 1, further comprising an insulating layer overlaying the electrode arrangement and said conductive tracks (see specification at page 9, lines 14-20, and at page 10, lines 4-9).

Claim 13 depends from Claim 12 and claims the biosensor of Claim 12, wherein a layer of mesh is interposed between the electrode arrangement and the insulating

layer (see specification at page 11, lines 7-17).

Claim 14 depends from Claim 12 and claims the biosensor of Claim 12, wherein a capillary space is interposed between the electrode arrangement and the insulating layer (see specification at page 10, lines 8-13).

Claim 15 depends from Claim 1 and claims the biosensor of Claim 1, further comprising a layer of tape overlying the electrode arrangement and the conductive tracks (see specification at page 11, lines 10-13).

Independent Claim 16 claims a biosensor for determining the concentration of an analyte in a liquid sample (see specification at page 1, lines 6-9). The biosensor comprises (a) a first substrate having two major surfaces (see specification at page 22, lines 13-16), (b) a second substrate having two major surfaces (see specification at page 22, lines 16-19), (c) a working electrode disposed on one major surface of the first substrate, the working electrode comprising a conductive ink, wherein the conductive ink comprises at least one enzyme, at least one mediator, and a polymer that provides hydrophilic domains in the conductive ink (see specification at page 20, lines 26-34 and at page 21, lines 1-5), (d) a second electrode disposed on one major surface of the second substrate (see specification at page 21, lines 26-29), (e) a first conductive track leading from the working electrode to an electrical contact associated with the working electrode, (f) a second conductive track leading from the second electrode to an electrical contact associated with the second electrode (see specification at page 21, lines 29-33, and at page 22, lines 1-2), and (g) an insulating layer disposed between the working electrode and the second electrode, wherein the major surface bearing the working electrode faces the major surface bearing the second electrode (see specification at page 22, lines 19-24).

Claim 18 depends from Claim 16 and claims the biosensor of Claim 16, wherein the at least one mediator is selected from the group consisting of organomettalic compounds, organic compounds, and coordination compounds with inorganic or organic ligands (see specification at page 17, lines 14-17).

Claim 21 depends from Claim 16 and claims the biosensor of Claim 16, wherein the biosensor requires a low volume of sample to trigger an electrochemical reaction (see specification at page 16, lines 1-3, and at page 22, lines 10-12).

Claim 22 depends from Claim 16 and claims the biosensor of Claim 16, wherein

spacing between the working electrode and the at least one other electrode does not exceed about 200 micrometers (see specification at page 16, lines 7-11).

Claim 23 depends from Claim 16 and claims the biosensor of Claim 16, wherein the working electrode has an area of from about 0.5 mm^2 to about 5 mm^2 (see specification at page 14, lines 17-20, and at page 15, lines 26-31).

Claim 24 depends from Claim 16 and claims the biosensor of Claim 16, wherein the biosensor further comprises a trigger electrode (see specification at page 10, lines 18-25).

Claim 25 depends from Claim 16 and claims the biosensor of Claim 16, wherein the biosensor further comprises a third electrode (see specification at page 10, lines 26-31).

Claim 26 depends from Claim 25 and claims the biosensor of Claim 25, wherein the biosensor further comprises a fourth electrode, the fourth electrode having the function of a trigger electrode (see specification at page 10, lines 32-34, and at page 11, lines 1-2).

Claim 27 depends from Claim 16 and claims the biosensor of Claim 16, wherein the layer of mesh is interposed between the working electrode and the insulating layer (see specification at page 11, lines 7-17).

Claim 28 depends from Claim 16 and claims the biosensor of Claim 16, wherein a capillary space is interposed between the working electrode and the insulating layer (see specification at page 10, lines 8-13).

Claim 29 depends from Claim 1 and claims the biosensor of Claim 1, wherein the enzyme is a dehydrogenase (see specification at page 17, lines 4-9).

Claim 30 depends from Claim 16 and claims the biosensor of Claim 16, wherein the enzyme is a dehydrogenase (see specification at page 17, lines 4-9).

Independent Claim 31 claims a biosensor for determining the concentration of an analyte in a liquid sample (see specification at page 1, lines 6-9). The biosensor comprises (a) an electrode support (see specification at page 9, lines 2-4), (b) a first electrically conductive track disposed on the electrode support, the track including a working electrode portion, a contact portion exposed for contact with a meter, and a conductive track portion electrically coupled between the working electrode portion and the contact portion (see specification at page 14, lines 31-34, and at page 15, lines 1-2),

wherein the working electrode portion contains intermixed conductive ink, wherein the conductive ink comprises an enzyme, mediator, and a polymer that provides hydrophilic domains in the conductive ink (see specification at page 20, lines 26-34 and at page 21, lines 1-5), and (c) a second electrically conductive track spaced from the first electrically conductive track and including a second contact portion exposed for contact with a meter (see specification at page 14, lines 31-34, and at page 15, lines 1-2).

Claim 32 depends from Claim 31 and claims the biosensor of Claim 31, wherein the polymer that provides hydrophilic domains in the conductive ink is polyethylene glycol (see specification at page 20, lines 25-27).

Claim 33 depends from Claim 1 and claims the biosensor of Claim 1, wherein the polymer that provides hydrophilic domains in the conductive ink is polyethylene glycol (see specification at page 20, lines 25-27).

Claim 34 depends from Claim 16 and claims the biosensor of Claim 16, wherein the polymer that provides hydrophilic domains in the conductive ink is polyethylene glycol (see specification at page 20, lines 25-27).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 3, 6-11, 29, and 31 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Say et al (USP 6,103, 033) in view of Charlton et al (USP 5,798,031). Claims 1, 3, 6-16, 18, and 21-31 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Feldman et al (USP 6,299,757) in view of Say, and in further view of Charlton. Claims 32-34 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Say in view of Charlton, and in further view of Yamashita et al (USP 5,472,590).

Thus, Appellants request review of the following grounds for rejection:

I. The Appellants request review of the ground for rejection of Claims 1, 3, 6-16, 18, and 21-34 under 35 U.S.C. § 103(a) as being unpatentable over Say et al in view of Charlton et al.

ARGUMENT

I. Claims 1, 3, 6-16, 18, and 21-34 are patentable under 35 U.S.C. § 103(a) over Say et al in view of Charlton et al.

All pending claims are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Say et al (U.S. Patent No. 6,103,033) in view of Charlton et al (U.S. Patent No. 5,798,031). Herein, the Appellants respectfully demonstrate that the Examiner's asserted *prima facie* case of obviousness is deficient.

In *Graham v. John Deere*, the Supreme Court set out a framework for applying the statutory language of 35 U.S.C. § 103. *Graham v. John Deere*, 383 US 1; 148 USPQ 459 (1966). This framework was reiterated in the Court's recent *KSR v. Teleflex Inc.* opinion, as follows:

> "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or non-obviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented."

KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1734 (2007).

The above framework may be restated as the following four factual inquires:

(A) Determining the scope and contents of the prior art;

(B) Ascertaining the differences between the prior art and the claims in issue;

(C) Resolving the level of ordinary skill in the pertinent art; and

(D) Evaluating evidence of secondary considerations.

With respect to framework elements A and B, courts have held that the reference or references cited in a rejection based on obviousness must teach or suggest all the elements of the claimed invention. "Subsumed within the Graham factors is a subsidiary requirement articulated by this court that where, as here, all claim limitations are found in a number of prior art references, the burden falls on the

challenger of the patent to show by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." Pfizer v. Apotex, 82 U.S.P.Q.2d 1321, 1330 (March 22, 2007). *See also Pharmastem Therapeutics v. Viacell et al.*, 83. U.S.P.Q. 2d 1289, 1302 (Fed. Cir. 2007) ("the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make [every element of] the composition or device, or carry out the [entire] claimed process, and would have had a reasonable expectation of success in doing so," (*citing KSR Int'l Co. v. Teleflex Inc.*, 82. U.S.P.Q.2d 1385 (2007); *and see Omegaflex, Inc. v. Parker-Hannifin Corp.*, 2007 U.S. App. LEXIS 14308 (Fed. Cir. 2007) ("[t]he Supreme Court recently explained that 'a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art,' (*citing KSR Int'l Co.* at 1741); *and see Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 80 U.S.P.Q.2d 1641, 1646 (Fed. Cir. 2006) ("[once] all claim limitations are found in a number of prior art references, the factfinder must determine '[w]hat the prior art teaches, whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references,' (*citing In re Fulton*, 391 F.3d 1195, 1199-1200 (Fed. Cir. 2004))).

The requirement that the combination of references teaches or suggests all elements of the claimed invention has been endorsed by the Patent & Trademark Office. According to the post-KSR Patent Office promulgated examination guidelines on determination of obviousness, when office personnel reject claims by attempting to combine prior art elements according to allegedly known methods to yield predictable results, the Office must resolve the *Graham* factual inquiries and articulate:

(1) "a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;"

(2) "a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element

merely would have performed the same function as it did separately; and"

(3) "a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable." (Federal Register / Vol. 72, No. 195 / Wednesday, October 10, 2007 / Notices at 57529, *citing KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395 (US 2007)).

Thus, the rationale to support a conclusion that a claim would have been obvious is that "all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions," and that "the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention." *Id.* at 57529.

In *KSR*, the Court noted that any analysis supporting a rejection under § 103(a) must be made explicit, and that it is "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements in the manner claimed." *KSR*, 127 S. Ct. at 1741. Put another way, the Court stated that it is important to "determine whether there was an apparent reason to combine the known elements in the way a patent claims." *Id.* "This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.*

It is respectfully submitted that the Examiner's *prima facie* case of obviousness is deficient because the combined teachings of the cited prior art references fail to render the claimed invention obvious. The Examiner has failed to demonstrate that one of ordinary skill in the art could have combined the elements as claimed, using known methods. Further, the Examiner has failed to demonstrate that one of ordinary skill in the art would have recognized that the results of the combination were predictable.

The claims are directed to a biosensor that includes an arrangement of electrodes. The claimed electrodes include a conductive ink, at least one enzyme, at least one mediator, and a polymer that provides hydrophilic domains in the conductive ink.

Thus, an element of the claims is an electrode that comprises conductive ink, at least one enzyme, at least one mediator, and a polymer that provides hydrophilic domains in the conductive ink.

Charlton Does Not Remedy the Deficiencies of Say

The Examiner asserts that Say et al teaches the invention substantially as claimed, but is deficient in that Say does not explicitly disclose the use of a polymer that provides hydrophilic domains, and therefore does not teach incorporation of a hydrophilic polymer into the conductive ink of the electrode. To resolve this deficiency, the Examiner relies on Charlton et al for teaching that the enzyme can be deposited in the presence of a hydrophilic polymer in a reagent layer over the surface of an electrode.

The Appellants respectfully disagree with the Examiner's assertion that Charlton remedies the identified deficiencies of Say. While Charlton suggests that the enzyme in the reaction layer can be combined with a hydrophilic polymer, **it does not teach that the hydrophilic polymer can be incorporated into the conductive ink of the electrode.** Only the present application teaches that the hydrophilic polymer can actually be incorporated directly into the conductive ink of the electrode.

In the Office Action of September 8, 2008, the Examiner correctly states that Charlton teaches mixing the enzyme with the hydrophilic polymer so that the two are intermixed in a single layer. In rejecting the instant claims, however, the Examiner pushes this teaching too far, suggesting that it would have been obvious for one of ordinary skill in the art to further mix the hydrophilic polymer into the conductive ink of the electrode simply because the enzyme is located within the conductive ink.

The concept of incorporating the polymer into the conductive ink of the electrode goes beyond merely combining elements of the cited prior art references. If combined properly, the Examiner's suggested combination of prior art elements would result in a sensor as described by Say with a layer of hydrophilic polymer deposited over the surface of the electrode, as described by Charlton.

The Examiner's assertion of obviousness is incorrect in the instant case because the suggested combination of prior art elements goes beyond mere combination of those elements as they exist in the cited prior art, and requires a combination of the elements in a way that is not disclosed in the cited prior art.

As such, the Examiner has clearly failed to establish that incorporation of the hydrophilic polymer into the conductive ink is merely a combination of known prior art elements using known methods. Therefore, the Examiner has failed to resolve the first *Graham* factual inquiry, *supra*, and an obviousness rejection is not justified.

The Proposed Modification Cannot Change the Principle of Operation of a Reference.

Under MPEP § 2143.01 (VI), if the proposed modification or combination of prior art references would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.

As noted above, the Examiner relies on Charlton for its teaching that the hydrophilic polymer and the enzyme can be deposited in a reagent layer over the surface of the electrode. The Examiner asserts that one of ordinary skill in the art would have read Charlton to suggest that the hydrophilic polymer should always be placed in the same location as the enzyme, and that incorporating the hydrophilic polymer into the conductive ink layer of Say would therefore have been obvious.

The Appellants respectfully submit that the Examiner's assertion ignores the fact that, based on the teachings of Charlton, incorporation of a hydrophilic polymer into the conductive ink of the electrode would impair the conductive properties of the electrode and would therefore change the principle of operation of the prior art invention. One of ordinary skill in the art would not anticipate that incorporating a hydrophilic polymer into the conductive ink of the electrode would allow the hydrophilic polymer to maintain its properties while also allowing the conductive ink to maintain its properties.

In addition to teaching that the enzyme can be mixed with a hydrophilic polymer to form a reagent layer over the surface of the electrode, Charlton also teaches that the components of the conductive ink are a mixture of carbon and silver, chosen to provide

a low chemical resistance path between the electrodes and the meter with which they are in operative connection (Charlton, Column 2, Lines 64-67). **Thus, Charlton teaches away from incorporating additional chemical moieties, such as a hydrophilic polymer, into the conductive ink because doing so might interfere with the conductive properties of the ink, rendering the electrode non-functional.** The Appellants respectfully submit that, contrary to the Examiner's assertion, one of ordinary skill in the art would therefore not be motivated to incorporate the hydrophilic polymer directly into the conductive ink. The Examiner has relied on one of Charlton's teachings, while conveniently ignoring another. In order to state a valid reason for making the proposed combination, **the Examiner must address *all* of the teachings in Charlton, not just those that are convenient for making a rejection in the instant case.**

One of ordinary skill in the art would have no expectation that the electrode could function properly if additional chemical moieties were incorporated into the conductive ink. The Examiner has failed to suggest a reason why one of ordinary skill in the art would think otherwise, and has therefore failed to satisfy the third *Graham* factual inquiry, *supra*. The Examiner's proposed modification would change the principle of operation of the prior art reference. Under MPEP 2143.01 § (VI), the teachings of the references are therefore not sufficient to render the claims *prima facie* obvious. As such, an obviousness rejection is not justified in the instant case.

SUMMARY

I. Claims 1, 3, 6-16, 18, and 21-34 are not made obvious under 35 U.S.C. § 103(a) over Say et al in view of Charlton et al because the cited references fail to demonstrate that one of ordinary skill in the art could have combined the elements as claimed, using known methods. The cited references further fail to demonstrate that one of ordinary skill in the art would have recognized that the results of the combination were predictable. As such, for at least the above listed reasons, the Examiner has failed to establish a *prima facie* case of obviousness, and the rejections should be reversed.

RELIEF REQUESTED

The Appellants respectfully request that the rejections of Claims 1, 3, 6-16, 18, and 21-34 under 35 U.S.C. § 103(a) be reversed, and that the application be remanded to the Examiner with instructions to issue a Notice of Allowance.

Respectfully submitted,

Date: November 7, 2008

By: /Edward J. Baba, Reg. No. 52,581/
Edward J. Baba
Registration No. 52,581

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, California 94303
Telephone: (650) 327-3400
Facsimile: (650) 327-3231

F:\DOCUMENT\ADCI\073\ADCI 073 Appeal Brief.doc

CLAIMS APPENDIX

1. A biosensor for determining the concentration of an analyte in a liquid sample, said biosensor comprising:

(a) an electrode support;

(b) an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode comprising conductive ink, wherein the conductive ink comprises at least one enzyme, at least one mediator, and a polymer that provides hydrophilic domains in the conductive ink,

(c) a first conductive track leading from the working electrode to an electrical contact associated with the working electrode; and

(d) a second conductive track leading from a second electrode to an electrical contact associated with the second electrode.

3. The biosensor of claim 1, wherein the at least one mediator is selected from the group consisting of organometallic compounds, organic compounds, and coordination compounds with inorganic or organic ligands.

6. The biosensor of claim 1, the biosensor requiring a low volume of sample to trigger an electrochemical reaction.

7. The biosensor of claim 1, wherein spacing between the working electrode and the second electrode does not exceed about 200 micrometers.

8. The biosensor of claim 1, wherein the working electrode has an area of from about 0.5 mm^2 to about 5 mm^2.

9. The biosensor of claim 1, wherein the electrode arrangement further comprises a trigger electrode.

10. The biosensor of claim 1, wherein the electrode arrangement further comprises a third electrode.

11. The biosensor of claim 10, wherein the electrode arrangement further comprises a fourth electrode, the fourth electrode having the function of a trigger electrode.

12. The biosensor of claim 1, further comprising an insulating layer overlying the electrode arrangement and said conductive tracks.

13. The biosensor of claim 12, wherein a layer of mesh is interposed between the electrode arrangement and the insulating layer.

14. The biosensor of claim 12, wherein a capillary space is interposed between the electrode arrangement and the insulating layer.

15. The biosensor of claim 1, further comprising a layer of tape overlying the electrode arrangement and the conductive tracks.

16. A biosensor for determining the concentration of an analyte in a liquid sample, the biosensor comprising:

(a) a first substrate having two major surfaces;

(b) a second substrate having two major surfaces;

(c) a working electrode disposed on one major surface of the first substrate, the working electrode comprising a conductive ink, wherein the conductive ink comprises at least one enzyme, at least one mediator, and a polymer that provides hydrophilic domains in the conductive ink:

(d) a second electrode disposed on one major surface of the second substrate;

(e) a first conductive track leading from the working electrode to an electrical contact associated with the working electrode;

(f) a second conductive track leading from the second electrode to an electrical contact associated with the second electrode; and

(g) an insulating layer disposed between the working electrode and the second electrode; wherein the major surface bearing the working electrode faces the major surface bearing the second electrode.

18. The biosensor of claim 16, wherein the at least one mediator is selected from the group consisting of organometallic compounds, organic compounds, and coordination compounds with inorganic or organic ligands.

21. The biosensor of claim 16, the biosensor requiring a low volume of sample to trigger an electrochemical reaction.

22. The biosensor of claim 16, wherein spacing between the working electrode and the at least one other electrode does not exceed about 200 micrometers.

23. The biosensor of claim 16, wherein the working electrode has an area of from about 0.5 mm^2 to about 5 mm^2.

24. The biosensor of claim 16, wherein the biosensor further comprises a trigger electrode.

25. The biosensor of claim 16, wherein the biosensor further comprises a third electrode.

26. The biosensor of claim 25, wherein the biosensor further comprises a fourth electrode, the fourth electrode having the function of a trigger electrode.

27. The biosensor of claim 16, wherein a layer of mesh is interposed between

the working electrode and the insulating layer.

28. The biosensor of claim 16, wherein a capillary space is interposed between the working electrode and the insulating layer.

29. The biosensor of claim 1, wherein the enzyme is a dehydrogenase.

30. The biosensor of claim 16, wherein the enzyme is a dehydrogenase.

31. A biosensor for determining the concentration of an analyte in a liquid sample, said biosensor comprising:

an electrode support;

a first electrically conductive track disposed on the electrode support, the track including a working electrode portion, a contact portion exposed for contact with a meter, and a conductive track portion electrically coupled between the working electrode portion and the contact portion, wherein the working electrode portion contains intermixed conductive ink, wherein the conductive ink comprises an enzyme, mediator and a polymer that provides hydrophilic domains in the conductive ink; and

a second electrically conductive track spaced from the first electrically conductive track and including a second contact portion exposed for contact with a meter.

32. The biosensor of claim 31, wherein the polymer that provides hydrophilic domains in the conductive ink is polyethylene glycol.

33. The biosensor of claim 1, wherein the polymer that provides hydrophilic domains in the conductive ink is polyethylene glycol.

34. The biosensor of claim 16, wherein the polymer that provides hydrophilic domains in the conductive ink is polyethylene glycol.

EVIDENCE APPENDIX

No evidence that qualifies under this heading has been submitted during the prosecution of this application, and as such it is left blank.

RELATED PROCEEDINGS APPENDIX

As stated in the *Related Appeals and Interferences* section above, there are no other appeals or interferences known to Appellants, the undersigned Appellants' representative, or the assignee to whom the inventors assigned their rights in the instant case, which would directly affect or be directly affected by, or have a bearing on the Board's decision in the instant appeal. As such this section is left blank.